Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
www.mass.gov/masshealth

MassHealth
Transmittal Letter ORT-27
May 2023

TO: Orthotic Services Providers Participating in MassHealth

FROM: Mike Levine, Assistant Secretary for MassHealth

RE: *Orthotics Manual* (Changes to Program Regulations Regarding Provider Enrollment, Member Notice)

Introduction

MassHealth has amended the orthotic (ORT) services regulation, 130 CMR 442.000, to update and clarify certain enrollment requirements, as described below. These regulations became effective April 28, 2023. The updates concern entities that are engaged in, and meet enrollment requirements for, multiple lines of business as providers of ORT, durable medical equipment (DME), oxygen and respiratory therapy equipment (OXY), or prosthetics (PRT) services. This transmittal letter also provides submission instructions for enrollment applications, billing instructions, and a reminder regarding notice to MassHealth and to members of changes in or updates to information in provider enrollment materials.

Definitions: 130 CMR 442.402

MassHealth has updated the definition of "ORT Provider" to support provider enrollment amendments.

Providers of ORT services may include qualified MassHealth enrolled OXY, DME, or PRT services who apply for and sign a provider contract to provide ORT services that meet all applicable requirements of 130 CMR 442.000 and 130 CMR 450.000.

Provider Eligibility: 130 CMR 442.404

MassHealth is expanding provider eligibility to OXY, DME, or PRT services providers who have completed a MassHealth orthotic services provider application and who meet all program-specific requirements. See 130 CMR 442.404(A).

The amendments to this regulation are designed to align with the OXY, DME, and PRT program regulations and:

- Remove the requirement that DME, OXY, ORT, or PRT services providers identify and enroll with, a primary line of business among these four provider types.
- Remove provisions that limit providers who otherwise meet all enrollment requirements for multiple lines of business to enrollment in only one additional program among these four provider types. For example, under the regulation in effect for enrollment applications filed before April 28, 2023, providers enrolled as DME providers may only additionally enroll as OXY providers and the reverse; ORT providers may only additionally enroll as PRT providers and the reverse.

- Remove the requirement that otherwise qualified providers of multiple lines of service maintain separate service locations for each line of business among the four provider types (DME, OXY, ORT, or PRT services).

Submission of Applications

Applications for new applicants or existing providers can be submitted

- Through the MassHealth LTSS Provider Portal at the URL listed at the end of this Transmittal Letter,
- By following instructions to complete the provider application process, or
- By filling out a paper application and submitting via email, fax, or mail to the addresses listed at the end of this Transmittal Letter.

Applicant enrolling with a **single** location must

- Complete a MassHealth provider enrollment application and identify the provider types (PT) they wish to enroll at the service location (DME, OXY, ORT, or PRT), and
- Complete a supplemental form for each PT identified on the application for the single service location.

Provider enrolling with **multiple** locations must

- Complete a MassHealth provider enrollment application listing **each location** and identify each of the PT they wish to enroll (DME, OXY, ORT, or PRT) at each service location, and
- Complete the appropriate supplemental form for each provider type identified on the application for each service location.

Existing MassHealth provider requesting to add a PT to a service location must

- Complete a MassHealth provider enrollment application listing each service location and identify the PT they wish to add to each service location, and
- Complete a supplemental form for each PT identified on the application for each service location.

Billing Instructions

Upon approval of a provider's application, a Provider Identification/Service Location number (PID/SL) will be provided.

Providers will be able to use this PID/SL to bill claims for the PT associated with each service location using the PID/SL linked to that location.

- Example: Service Location 1: 123456789A
  Service Location 2: 123456789B
  Service Location 3: 123456789C

Reminder: Provider Responsibility (130 CMR 442.405)

Providers are reminded that they must notify MassHealth of any changes to information submitted in their provider applications. Specifically, in addition to 130 CMR 450.215 and 130 CMR 450.223, MassHealth calls providers' attention to ORT regulation 130 CMR 442.405(B) and (T), which require that providers:

> **(**B) notify the MassHealth agency or its designee within 14 days of any changes in any of the information submitted in the provider application in accordance with 130 CMR 450.215: Provider Eligibility: Notification of Potential Changes in Eligibility and 130 CMR 450.223(B), including but not limited to, change of ownership, change of address, change in scope of service, and additional service locations. The provider may not bill for new service locations until approved by MassHealth. The provider must maintain records of all such communications and transactions and make such records available to the MassHealth agency or its designee for review upon request;

. . .

> (T) provide MassHealth members, currently being serviced by the provider with written notification at least 60 days in advance of any change in the ORT provider's scope of business or services (for example, if a provider decides to no longer provide certain products), or (if the scope of the provider's Medicare accreditation changes). Notification to the member must include:
>
> (1) a statement that the member can contact MassHealth Customer Service to request a list of ORT providers in their area; and
>
> (2) if prior authorization is required for the service
>
> (a) the number of non-billed units remaining on the PA; and
>
> (b) a copy of the original PA approval from MassHealth for the member to provide to the new ORT provider.

Prosthetic Providers Previously Enrolled with an Orthotic Specialty

Upon revalidation, PRT providers who choose to continue to provide ORT services will need to complete an ORT provider application.

Upon completing the required form, providers must list or attach all the ORT product categories their organization is accredited to provide. Providers can only be enrolled in MassHealth to provide accredited products.

MassHealth Website

This transmittal letter and attached pages are available on the MassHealth website at www.mass.gov/masshealth-transmittal-letters.

Sign up to receive email alerts when MassHealth issues new transmittal letters and provider bulletins.

Questions

If you have any questions about the information in this transmittal letter, please contact the LTSS Provider Service Center.

The MassHealth LTSS Provider Service Center is open from 8 am to 6 pm ET, Monday through Friday, excluding holidays. LTSS providers should direct questions about this transmittal letter or other MassHealth LTSS Provider questions to the LTSS Third Party Administrator (TPA) as follows:

Phone: Toll-free (844) 368-5184

Email: support@masshealthltss.com

Portal: www.MassHealthLTSS.com

Mail: MassHealth LTSS
PO Box 159108
Boston, MA 02215

FAX: (888) 832-3006

NEW MATERIAL

(The pages listed here contain new or revised language.)

Orthotics Manual

Pages iv, and 4-1 through 4-26.

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Orthotics Manual

Pages iv, and 4-1 through 4-24 — transmitted by Transmittal Letter ORT-25

4. Program Regulations

130 CMR 442.000: *Orthotics Services*

442.401: Introduction

130 CMR 442.000 states the requirements and procedures for the purchase and repair of orthotics covered under MassHealth. All providers of orthotics participating in MassHealth must comply with MassHealth regulations, including, but not limited to, regulations set forth in 130 CMR 442.000 and in 130 CMR 450.000: *Administrative and Billing Regulations* and 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices*.

442.402: Definitions

The following terms used in 130 CMR 442.000 have the meanings given in 130 CMR 442.402 unless the context clearly requires a different meaning. Conditions of coverage and payment for services defined in 130 CMR 442.000 are not determined by these definitions, but by application of regulations elsewhere in 130 CMR 442.000 and in 130 CMR 450.000: *Administrative and Billing Regulations*.

Adjusted Acquisition Cost — except where the manufacturer is the provider, the price paid by the provider to the manufacturer or any other supplier for orthotic or pedorthic devices, customized equipment, or supplies, excluding all associated costs such as shipping, handling, and insurance costs in accordance with 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices*. As provided in 101 CMR 334.00, where the manufacturer is the provider, the adjusted acquisition cost cannot exceed the actual cost of the raw materials.

American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC) — a national certifying and accrediting body for the orthotic, prosthetic and pedorthic professions, recognized as a deemed authority for facility accreditation by CMS.

American Standard Last Sizing Schedule — the numerical shoe sizing system used for shoes in the United States.

Board of Certification/Accreditation International (BOC) — BOC is an independent certifying and accrediting body for practitioners and suppliers of comprehensive orthotic and prosthetic care, and is recognized as a deemed authority for facility accreditation by CMS.

Centers for Medicare and Medicaid Services (CMS) — a federal agency responsible for administering the Medicaid and Medicare programs created under the authority of Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), and Title XVIII of the Social Security Act (42 U.S.C. 1395-1395pp).

Consignment Closet — an arrangement in which an orthotics provider maintains inventory at a prescribing provider's location, which is not the orthotics provider's service facility, for delivery to members on behalf of the orthotics provider.

Custom-fabricated — an orthotic made for a specific patient from his/her individual measurements and/or pattern.

Custom-fitted/prefabricated — a prefabricated device or product that has been manufactured from standard molds or patterns and that requires substantial modification for fitting from an ABC- or BOC-certified orthortist or an individual who has equivalent specialized training.

Custom-molded Shoe — an individually patterned shoe fabricated to meet the specific needs of an individual. A custom-molded shoe is not off-the-shelf, stock, or prefabricated. The shoe is individually constructed by a molded process over a modified positive model of the individual's foot. It is made of leather or other suitable material of equal quality, has removable customized inserts that can be replaced if necessary according to the individual's condition, and has some form of shoe closure.

Date of Service — the date of service as specified in 130 CMR 442.424, as applicable, for delivery of the final orthotic product or service to the member, or as specified in 130 CMR 442.406(D), consistent with 130 CMR 450.231: *General Conditions of Payment*, for custom fabricated items ordered but not furnished to a member.

Detailed Written Order — the written prescription and statement of medical necessity justification for the specified orthotic services from the member's prescribing provider that meets the requirements at 130 CMR 442.409.

EOHHS — the Executive Office of Health and Human Services established under M.G.L. c. 6A.

Fitter of Therapeutic Shoes for Diabetics — an individual who is educated and trained in the provision of non-custom therapeutic shoes for diabetics and non -custom multi-density inserts including patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

Foot Deformity — a deformity of the foot that may be congenital or acquired, where the foot is no longer in normal anatomical position, proportion or alignment.

Healthcare Common Procedure Coding System (HCPCS) — for purposes of 130 CMR 442.000, HCPCS refers to the Level II HCPCS codes which are maintained by CMS, adopted by the MassHealth agency and used by providers to bill for certain medical services, devices, and supplies, including all orthotic services.

Home — for the purposes of the provision of orthotics, a member's home may be a dwelling owned or rented by the member, relative's or other person's home in which the member resides, a rest home, assisted living, or another type of group residence in a community setting in which normal life activities take place. A home does not include an institutional setting including but not limited to, a hospital, nursing facility or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board, except for items that are allowable pursuant to 130 CMR 442.410.

Hospital — a facility that is licensed or operated as a hospital by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health that provides diagnosis and treatment on an inpatient or outpatient basis for patients who have any of a variety of medical conditions.

Initial Order —a written, electronically submitted or documented verbal communication from the member's prescribing provider to the provider of orthotics to assess and evaluate the member for the specified orthotic service, and which meets the requirements of 130 CMR 442.409.

Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) — a facility, or distinct part of a facility, that provides intermediate care facility services as defined under 42 CFR 440.150, and that meets Federal conditions of participation, and is licensed by the State primarily for the diagnosis, treatment, or rehabilitation for individuals with intellectual disabilities; and provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration for health or rehabilitative services to help individuals function at their greatest ability.

Last — a model that approximates the shape and size of the foot and over which a shoe is made. A last is usually made of wood, plastic, or plaster.

MassHealth — the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), M.G.L. c.118E, and other applicable laws and waivers to provide and pay for medical services to eligible members.

Medicare — a federally administered health insurance program for persons eligible under the Health Insurance for the Aged Act, Title XVIII of the Social Security Act (42 U.S.C. 1395-1395pp).

Member — a person determined by the MassHealth agency to be eligible for MassHealth.

Nonstandard Size (Width or Length) — a shoe size made on a standard last pattern, but which is not part of a manufacturer's regular inventory.

Nursing Facility (NF) — an institution or distinct part of an institution licensed and certified for participation in Medicaid and Medicare by the Massachusetts Department of Public Health that is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured people, people with disabilities, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services that meets the requirements of the Social Security Act, §§ 1919 (a), (b), (c) and (d).

Nurse Practitioner — a registered nurse who has successfully completed a formal education program for nurse practitioners as required by the Massachusetts Board of Registration of Nursing (the Board), who is in good standing with the Board, and who is responsible for oversight of the member's health care. A nurse practitioner who prescribes medication must be certified by the federal Drug Enforcement Agency (DEA).

Off-the-shelf — A prefabricated device or product that requires minimal self-adjustment as defined at 42 CFR 414.402 for appropriate use, *i.e.*, does not require the services of an ABC- or BOC-certified orthotist or an individual who has equivalent specialized training to adjust the device.

Off-the-shelf Shoe — a shoe that is made on a standard last and is a regular part of a manufacturer's or provider's inventory.

Orthopedic Shoes — shoes that are specially constructed to aid in the correction of a deformity of the musculoskeletal structure of the foot and to preserve or restore the function of the musculoskeletal system of the foot.

Orthosis — a device that is:

(1) used to support, align, correct, or prevent deformities of the body, which may be used to eliminate, control, or assist motion at a joint or body part; and

(2) appropriate for use in the member's home or any setting in which normal life activities take place in the community.

Orthotic Assistant — an individual educated and trained to participate in comprehensive orthotic care while under the supervision of an ABC- or BOC-certified orthotist. An orthotic assistant may perform orthotic procedures and related tasks in the management of members, including fabricating repairs and maintaining orthotic devices to provide maximum fit and function.

Orthotic Services — the provision, purchase, customization, fitting, repair, replacement, or adjustment of an orthosis, orthotic supply, device, or component part, or other activity performed in accordance with 130 CMR 442.000.

Orthotic Supplies — products that are:

(1) fabricated primarily and customarily to fulfill a medical or surgical need;
(2) used in conjunction with an orthosis or orthotic equipment;
(3) generally not useful in the absence of an orthosis; and
(4) nonreusable and disposable.

Orthotics — products that are fabricated primarily and customarily to fulfill a medical or surgical need, and are generally not useful in the absence of illness, injury or disability. Pedorthic Services are a subset of Orthotics.

Orthotics Fitter — an individual who is educated and trained in the provision of certain prefabricated orthoses, including patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

Orthotics and Prosthetics Payment and Coverage Guidelines Tool — MassHealth web-based application that contains orthotics and prosthetics service descriptions for products, services, applicable modifiers, place-of-service codes, prior authorization requirements, individual consideration requirements, service limits, markup information, and links to other applicable information, such as MassHealth pricing information and additional or updated guidance issued by the MassHealth agency or its designee. The *Orthotics Manual*, *Subchapter 6* directs providers to the Orthotics and Prosthetics Payment and Coverage Guidelines Tool.

Orthotics Provider – an organization or individual that has enrolled with MassHealth and has signed a provider contract with the MassHealth agency who meets all applicable requirements of 130 CMR 442.404 and 450.000: *Administrative and Billing Regulations*. Orthotics providers may include providers also enrolled as MassHealth participating durable medical equipment (DME) and supplies providers, oxygen and respiratory therapy equipment and supplies (OXY) providers, or prosthetic services providers, who meet all program-specific requirements.

Orthotist — an individual who is noncertified or ABC- or BOC-certified and is specifically educated and trained to manage comprehensive orthotic care, including patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

Pedorthic Service — a subset of orthotic services involving the design, manufacture, modification, and fitting of orthopedic shoes, or the fitting of therapeutic shoes for diabetics, including foot orthoses, prosthetic fillers, and orthotic or pedorthic appliances for use from the ankle and below, for the prevention or amelioration of painful and/or disabling conditions of the foot and ankle, and as provided in accordance with 130 CMR 442.000.

Pedorthist — an individual who is noncertified or ABC- or BOC-certified, and is specifically trained and educated to manage comprehensive pedorthic care, including patient assessment, custom-molding, formulation of a treatment plan, implementation of a treatment plan, follow-up and practice management.

Physician Assistant — a mid-level medical practitioner who works under the supervision of a licensed physician (MD) or osteopathic physician (DO) and who is licensed to practice as a physician assistant by the Massachusetts Board of Registration of Physician Assistants or by the licensing agency of another state, and provides health care services to the member.

Prescribing Provider — a physician, doctor of osteopathy (DO), nurse practitioner, physician assistant, or podiatrist who prescribes and writes the prescription for all orthotics and orthotic services.

Pricing, Data Analysis, and Coding (PDAC) — a CMS contractor that evaluates and processes coding verification applications from manufacturers for Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) for Medicare purposes. The PDAC also establishes, maintains and updates all coding verification decisions on the PDAC Product Classification List that is available on the Durable Medical Equipment Coding System (DMECS), which is an official source for Medicare DMEPOS product code verification and HCPCS service code assignment, and also provides coding guidance on the appropriate HCPCS service codes for DMEPOS suppliers to use when submitting DMEPOS claims to Medicare, including for orthotics.

Proof of Delivery (POD) — documentation, such as a delivery slip, that indicates that the orthotics provider delivered, or had shipped, to a specified MassHealth member, the orthotics that were intended for that member, and that the member received the orthotics.

Prior Authorization (PA) Request — a request submitted by the orthotics provider, to the MassHealth agency to determine medical necessity in accordance with 130 CMR 442.412, 450.204: *Medical Necessity*, and 450.303: *Prior Authorization*.

Service Facility — an orthotics provider's place of business (excludes a member's place of residence), where MassHealth members can obtain all orthotic services, including those involving fitting, adjustment, repair, and replacement of orthoses.

Split-size Charge — an additional charge for dispensing an off-the-shelf, medical-grade pair of orthopedic shoes, where one shoe in the pair is a different size or width than the other shoe in the pair.

Therapeutic Shoes for Diabetics — therapeutic footwear prescribed by the prescribing provider to prevent or alleviate painful or disabling conditions associated with diabetes by minimizing pressure on the foot.

442.403: Eligible Members

(A) MassHealth Members. The MassHealth agency covers orthotics provided to eligible MassHealth members, subject to the restrictions and limitations described in 130 CMR 442.000 and 450.000: *Administrative and Billing Regulations*. 130 CMR 450.105: *Coverage Types* specifically states, for each coverage type, which services are covered and which members are eligible to receive those services.

(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, *see* 130 CMR 450.106: *Emergency Aid to the Elderly, Disabled and Children Program*.

(C) For information on verifying MassHealth member eligibility and coverage type, *see* 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

442.404: Provider Eligibility

(A) Provider Participation Requirements. Payment for services described in 130 CMR 442.000 is made to orthotics providers who, as of the date of service, are participating in MassHealth as an orthotics provider; to providers also enrolled as MassHealth participating DME providers; OXY providers, or prosthetic services providers and who meet all program-specific requirements. Applicants must meet the requirements in 130 CMR 450.000: *Administrative and Billing Regulations* as well as the requirements in 130 CMR 442.000. Participating orthotics providers must continue to meet provider eligibility participation requirements throughout the period of their provider contract with the MassHealth agency.

(B) General Qualifications. To qualify as a MassHealth orthotics provider, all applicants and providers must enter into a provider contract or agreement with MassHealth and

(1) have a service facility that:
   (a) is open a minimum of 30 hours per week;
   (b) is staffed with an employee during posted business hours;
   (c) is available to members during regular, posted business hours;
   (d) is physically accessible to members with disabilities, and complies with all ADA guidelines;
   (e) has clear access and space for individualized ordering, returns, repair, and storing of business records;

(f) has the space and capability for evaluating/assessing, repairing, modifying, adjusting and customizing products to meet members' needs;
(g) the provider can demonstrate their ability to fill orders, fabricate, or fit items from their own inventory or by direct purchase of items necessary to fill the order.
(h) has a sign visible from outside the service facility identifying the business name and hours that the service facility is open. If the provider's place of business is located within a building complex, the sign must be visible with the business name both at the main entrance of the building and the location where the service facility is located. The hours must be posted within the business complex where the service facility is located;
(i) has a primary business telephone number listed in the name of the business with a local toll-free telephone number that is answered by customer service staff during business hours, and that has TTY transmission and reception capability. During business hours, this number cannot exclusively be a pager, answering service, voice message system, or cell phone; and
(j) maintains a 24-hour voice message system and/or answering service.

(2) obtain separate approval from the MassHealth agency or its designee and a separate provider number for each service facility operated by the provider;
(3) engage in the business of providing orthotics or orthotic repair services to the public;
(4) participate in the Medicare program as a provider;
(5) have a Medicare provider number for each business and service facility and location for which it is applying to participate or participating in MassHealth:
(6) be accredited by the American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC), or the Board of Certification/Accreditation International (BOC) as a comprehensive orthotics facility, and display such accreditations at service facility locations;
(7) for each service facility, maintain fulltime coverage by an ABC- or BOC-certified orthotist or orthotists responsible for overall patient care and for providing or supervising the noncertified orthotists for the provision of comprehensive orthotic services at that service facility. A noncertified orthotist must be employed by the MassHealth-enrolled Orthotics provider;
(8) ensure that any professional staff from the disciplines listed in 130 CMR 442.404(B)(8)(a) through (d), who provide orthotic services to members meet the requirements set forth in 130 CMR 442.404(B)(8)(a) through (d), for their respective disciplines, and that the services provided are within their scope of practice and training.

(a) An orthotics fitter must be ABC- or BOC-certified or work under the supervision of an ABC or BOC-certified orthotist, and be employed by the MassHealth Orthotics provider.
(b) A fitter of therapeutic shoes for diabetics must be ABC- or BOC-certified or work under the supervision of an ABC- or BOC-certified orthotist or ABC- or BOC-certified pedorthist, and be employed by the MassHealth Orthotics provider.
(c) An Orthotic assistant must be ABC- or BOC-certified or work under the supervision of an ABC- or BOC-certified orthotist, and be employed by the MassHealth Orthotics provider.
(d) A pedorthist may be ABC- or BOC-certified or may be noncertified. A non-certified pedorthist must work under the supervision of an ABC- or BOC-certified orthotist or ABC- or BOC-certified pedorthist. All pedorthists must be employed by the MassHealth-enrolled orthotics provider.

(9) meet all applicable federal, state, and local requirements, including requirements for certifications and registrations;
(10) at the time of application and recredentialing, or any other time as requested by the MassHealth agency or its designee, and provide all required documentation specified in 130 CMR 450.000: *Administrative and Billing Regulations* and 450.215: *Provider Eligibility: Notification of Potential Changes in Eligibility*, including:
(a) all current liability insurance policies;
(b) the property lease agreement(s) for each service facility, or a copy of the most recent property tax bill if applicant owns the business site;
(c) all current signed employee professional credentials, as applicable;
(d) the current facility ABC or BOC accreditation letter; and
(e) the purchase and sale agreement if the applicant or orthotics provider has recently purchased the company for which they are applying to become a MassHealth provider;
(11) provide, or make available upon request, a copy of written policies and procedures, including the customer service protocol, customer complaint tracking and resolution protocol, and staff training;
(12) conduct Criminal Offender Record Information (CORI) checks on employees and subcontractors in accordance with procedures outlined in EOHHS CORI regulations at 101 CMR 15.00: *Criminal Offender Record Checks*, and conducting applicable Office of Inspector General (OIG) verifications on all personnel;
(13) not accept prescriptions from any prescribing provider who has a financial interest in the orthotics provider or any prescribing provider who is employed by an entity that has a financial interest in the orthotics provider;
(14) cooperate with the MassHealth agency or its designee during the application and recredentialing process and record reviews, including agreeing to periodic inspections to ensure compliance with 130 CMR 442.000 and applicable state and federal laws and regulations;
(15) establish, maintain, and comply with written policies and procedures in accordance with 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*; and
(16) agree to participate in any orthotic provider orientation or any other training required by EOHHS.

(C) In-state. To participate in MassHealth as an in-state orthotics provider, the applicant or provider of orthotics must have a service facility in Massachusetts that meets the criteria described in 130 CMR 442.404 (B), and must meet all other criteria described in 130 CMR 442.404.

(D) Out of state. To participate in MassHealth as an out of state orthotics provider, an applicant or provider of orthotics must meet all of the following conditions:
(1) the provider participates in the Medicare program, and participates in the medical assistance program of the state in which the provider primarily conducts business;
(2) the provider meets all applicable requirements under 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, and 42 CFR 431.52; and
(3) The MassHealth agency or its designee has determined that the out-of-state provider provides orthotics that meets a MassHealth-identified agency need.

442.405: Provider Responsibilities

In addition to meeting all other provider requirements set forth in 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, the provider of orthotics must:

(A) accept rates of payment established by the Executive Office of Health and Human Services as set forth in 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices* for all orthotic services provided to MassHealth members, unless otherwise determined by the MassHealth agency or its designee through a selective contracting, preferred provider, or other process;

(B) notify the MassHealth agency or its designee within 14 days prior to any changes in any of the information submitted in the provider application in accordance with 130 CMR 450.215: Provider Eligibility: Notification of Potential Changes in Eligibility and 130 CMR 450.223(B) including, but not limited to, change of ownership, change of address, change in scope of service, and additional service locations. The provider may not bill for new service locations until approved by MassHealth. The provider must maintain records of all such communications and transactions and make such records available to the MassHealth agency or its designee for review upon request;

(C) ensure that the orthotic services provided are consistent with industry quality standards or any applicable standards established by the MassHealth agency, given the medical need for which the orthotics are prescribed and the member's functional limitations;

(D) ensure prompt amelioration, repair or replacement of all orthoses or other orthotic services that have been provided to a member and which are subject to recall, in accordance with the specifications in the recall notice. The orthotics provider shall provide the member with a copy of the recall notice and fully address the recall as specified in the recall instructions no later than five business days from the date the orthotic provider receives the recall notice;

(E) evaluate and access the member's need for orthotic services, and for delivery of the product(s) to the member either at the orthotic provider's service facility location or other setting as deemed appropriate by the member and the orthotics provider, including education of the member, or caregivers, as appropriate, in the use of the product;

(F) ensure that all orthotic services are furnished to MassHealth members by employees of the orthotics provider, and that such employees are qualified in their respective disciplines to perform the orthotic services that they provide, consistent with 130 CMR 442.404(B)(8);

(G) comply with MassHealth administrative and billing regulations at 130 CMR 450.000: *Administrative and Billing Regulations*, including any third party liability or member cost-sharing requirements;

(H) comply with applicable state and federal third party liability requirements for MassHealth members with other insurance, including dually eligible members. This includes compliance with state and federal law and other subregulatory requirements necessary to obtain payment from other liable parties;

(I) comply with all applicable Medicare billing and authorization requirements and make diligent efforts to identify and obtain payment from all other liable parties including Medicare, before billing MassHealth, in accordance with 130 CMR 450.316: *Third-party Liability: Requirements*. This includes appealing a denied claim when the service is payable in whole or in part by Medicare or other liable parties or payers;

(J) report to the proper authorities any suspected abuse or neglect that staff may observe when providing service to a member, as mandated by M.G.L. c.19A, §15. M.G.L.c.19C, §10, M.G.L. c.111, §72G, M.G,L. c.119m §51A, , in addition to any other suspected abuse or neglect as required by other state and federal law;

(K) adhere to the Medicare supplier standards set forth by CMS;

(L) not alter any invoice or medical documentation;

(M) not solicit members to purchase additional orthotic services;

(N) submit prior-authorization requests, as specified by 130 CMR 442.412, to the MassHealth agency, or its designee. Prior authorization requests should only be submitted when the orthotic service is medically necessary and when prior-authorization is a prerequisite in accordance with 130 CMR 442.412, and when other MassHealth guidance requires it;

(O) respond to members' complaints or complaints made on behalf of a member within two business days;

(P) not share a service facility or physical location (including a consignment closet, unless permitted by specific MassHealth guidance) with a provider who is authorized to prescribe orthotics, or with another orthotics provider, except as permitted by 42 CFR 424.57(C)(29)(ii) (Medicare Supplier Standard 29);

(Q) have a complaint resolution protocol to promptly address members' complaints and keep written complaints, related correspondence, and any notes of actions taken in response to written and oral complaints, and maintain such information in accordance with 130 CMR 442.423(I). This includes responding to any member complaints within two business days;

(R) ensure that the member and the member's caregivers, as appropriate, can use all orthotics provided safely and effectively in the settings of anticipated use;

(S) comply with applicable CMS and MassHealth quality standards and any applicable quality measurement program requirements; and

(T) provide MassHealth members, currently being serviced by the provider, with written notification at least 60 days in advance of any change in the orthotics provider's scope of business or services (for example, if a provider decides to no longer provide certain products), or if the scope of the provider's Medicare accreditation changes). Notification to the member must include:

(1) a statement that the member can contact MassHealth Customer Service or other agency designee to request a list of MassHealth participating Orthotics providers in their area;

2) offer assistance to the member regarding transfer of services to another provider if appropriate; and

(3) if prior authorization is required for the service:

(a) information about any unbilled units remaining on the PA; and

(b) a copy of the original PA approval from MassHealth for the member to provide to the new orthotics provider.

442.406: Covered Services

(A) The MassHealth agency pays for medically necessary orthotics and orthotic services pursuant to the governing of the *Orthotics Manual*, Subchapter 6; the Prosthetics Payment and Coverage Guidelines Tool; and any other guidance issued by the MassHealth agency or its designee. MassHealth covers orthotics that are appropriate for use in the member's home or any setting in which normal life activities take place in the community, subject to the requirements of 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, including 130 CMR 450.204: *Medical Necessity*.

(B) Therapeutic Shoes for Diabetics, Inserts and Modifications. MassHealth covers therapeutic shoes for diabetics, inserts and modifications under the following conditions, subject to compliance with 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*:

(1) MassHealth covers therapeutic shoes for diabetics only when prescribed by a DO or MD.

(2) In all cases, the member must have a documented diagnosis of diabetes mellitus and meet one or more of the following conditions:

(a) previous amputation of the other foot, or part of either foot;

(b) history of previous foot ulceration of either foot;

(c) history of pre-ulcerative calluses of either foot;

(d) peripheral neuropathy with evidence of callus formation of either foot;

(e) foot deformity of either foot (must clearly indicate the foot deformity); or

(f) poor circulation in either foot.

(3) For non-custom therapeutic shoes for diabetics, the shoe must meet all of the following guidelines in addition to the member meeting the requirements of 130 CMR 442.406(B)(2):

(a) contain a full length, heel-to-toe filler that when removed provides a minimum of 3/16" of additional depth used to accommodate custom molded or customized inserts;

(b) be made from leather or suitable material of equal quality;

(c) have some form of shoe closure; and

(d) be available in full and half sized with a minimum of three widths so that the shoe is graded to the size and width of the upper portion of the shoe according to the American Standard last sizing schedule or its equivalent. This includes a shoe with or without an internally seamless toe.

(4) For custom-molded therapeutic shoes for diabetics, the shoe must meet all of the following guidelines, in addition to the member meeting the requirements of 130 CMR 442.406(B)(2):

(a) be constructed over a positive model of the member's foot;

(b) be made from leather or suitable material of equal quality;

(c) have removable inserts that can be altered or replaced as the member's condition warrants; and

(d) have some form of shoe closure.

(C) Orthotics Other than Therapeutic Shoes for Diabetics, Inserts and Modifications. MassHealth covers orthotics and orthotic services other than therapeutic shoes for diabetics, inserts and modifications, in accordance with the guidelines described in the *MassHealth Orthotics and Prosthetics Payment and Coverage Guidelines Tool*, subject to compliance with 130 CMR 442.000 and 450.000: *Administrative and Billing Regulations*.

(D) Custom Fabricated Items Ordered but Not Furnished. 130 CMR 450.231: *Conditions of Payment*, governs payment for custom fabricated, fitted or altered items ordered for, but not furnished to, a member who ceases to be eligible for such items on a date prior to the final delivery. 130 CMR 450.231(C) and (D). Payment will be made based on materials used. Providers must maintain documentation demonstrating compliance with 130 CMR 450.231(C) and (D) including, but not limited to:

(1) the date of the member's last visit;
(2) the date that the provider fabricated the item, as defined in 130 CMR 450.231(C); and
(3) the first substantial step taken to initiate the production process after the conclusion of all necessary member visits.

442.407: Service Limitations

The MassHealth agency pays for all medically necessary orthotics subject to the service limitations set forth in 130 CMR 442.000; the *Orthotics Manual*, Subchapter 6 of*;* and the MassHealth Orthotics and Prosthetics Payment and Coverage Guidelines Tool, subject to the Early and Periodic Screening, Diagnosis, and Treatment provisions set forth in 130 CMR 450.144(A): *EPSDT Services: Diagnosis and Treatment*.

(A) Nonstandard Size (Width or Length). A provider may bill an additional charge for a nonstandard size for off-the-shelf, medical-grade orthopedic shoes once per pair.

(B) Split-size Change. A provider may bill a split-size charge for off-the-shelf, medical-grade orthopedic shoes once per pair.

(C) Custom-molded Shoe Inserts. When a manufacturer offers a custom-molded shoe that includes the insert, the provider of orthotics must not bill separately for the initial insert.

(D) Closure Modification. When a manufacturer offers an off-the-shelf shoe that comes standard with either lace or velcro enclosures, the provider of orthotics must choose the appropriate shoe to meet the member's needs, and not bill separately for closure modification.

442.408: Non-covered Services

MassHealth does not pay for any of the following:

(A) any orthotics for which, under comparable circumstances, the provider of orthotics does not customarily bill private patients who do not have health insurance;

(B) nonmedical items: items that are used primarily and customarily for a nonmedical purpose are not considered orthotics, even if the item has a medically related use;

(C) therapeutic shoes for diabetics that are not listed on the PDAC Product Classification List, with an associated HCPCS code;

(D) an additional charge for nonstandard size (width or length) in custom-molded shoes;

(E) orthotics that are not provided in accordance with the MassHealth Orthotics and Prosthetics Payment and Coverage Guidelines tool, or other guidance issued by the MassHealth agency or its designee;

(F) orthotics that are not reasonably expected to make a meaningful contribution to the treatment of a member's condition or the performance of the member's activities of daily living;

(G) orthotics that are not listed as covered services in Subchapter 6 of the *Orthotics Manual* and the *MassHealth Orthotics and Prosthetics Payment and Coverage Guidelines Tool* or any other guidance issued by the MassHealth agency or its designee unless prior authorization has been issued by the MassHealth agency or its designee;

(H) orthotics provided to members in facilities that are not permissible under 130 CMR 442.410;

(I) repairs that do not meet the requirements of 130 CMR 442.411, and 130 CMR 442.410 (if applicable);

(J) orthotics that are experimental or investigational in nature as described in 130 CMR 450.204 (E): *Medical Necessity*; and

(K) orthotics furnished through a consignment/stock and bill closet (unless permitted by specific MassHealth guidance).

442.409: Prescribing Provider Orders and Other Documentation Requirements

(A) Initial Orders. The initial order may be written, verbally, or electronically transmitted (in accordance the applicable federal and state laws, rules and guidance) by the member's prescriber. A verbal initial order must be simultaneously documented in writing by an employee of the provider of orthotics.

(1) The verbal, written, or electronically transmitted initial order must include:
   (a) the date the orthotics provider obtains or receives the initial order from the prescribing provider;
   (b) a general description of the orthotic service that is the subject of the initial order
   (c) the member's name;
   (d) the name of prescribing provider giving the initial order; and
   (e) the name and title of the employee of the provider of orthotics who obtained or received the initial order, and in the case of a verbal initial order, documented the initial order in writing.

(2) Orthotics providers must maintain a copy of the initial order (or written documentation of a verbal initial order) in the member's record and make this information available to MassHealth upon request.

(B) Detailed Written Order. The provider of orthotics must obtain a detailed written order signed and dated by the member's prescribing provider for all orthotic services provided to a member prior to the date the claim is submitted to MassHealth for the orthotic services, or in the case of orthotic services requiring prior authorization, prior to the date that the prior authorization request is submitted to the MassHealth agency or its designee. The detailed written order must comply with the requirements for a legal prescription under all applicable federal and state laws and regulations, and also contain a statement of medical necessity. If the detailed written order is prepared by the orthotics provider, the detailed written order must be reviewed, signed and dated by the prescribing provider. The detailed written order must contain an attestation whereby the prescribing provider certifies under pains and penalties of perjury, that he or she is the prescribing provider identified on the detailed written order; that the medical necessity information on and attached to the detailed written order is true, accurate, and complete to the best of his/her knowledge, and that the prescribing provider may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact pertaining thereto. For specific orthotic services, additional requirements apply as set forth in 130 CMR 442.409(B)(1) and (2).

(1) Shoes and Related Services.

(a) For therapeutic shoes, inserts, and modifications for diabetics, the orthotics provider and the prescribing provider must complete and sign the MassHealth Orthotic and Prosthetic Prescription and Medical Necessity Review Form for Therapeutic Shoes, Inserts, and Modifications (for diabetics) (Form ORT-D), or successor form adopted by MassHealth. This form serves as the detailed written order and statement of medical necessity. As a condition of payment, a copy of the completed form must be submitted to MassHealth with the provider's claim. The completed form must be maintained in the member's record.

(b) For foot orthoses, footwear (inclusive of orthopedic shoes) and modifications for non-diabetic members, the prescribing provider must complete and sign the MassHealth Orthotic and Prosthetic Prescription and Medical Necessity Review Form for Foot Orthoses, Footwear, and Modifications (for non- diabetics) (Form ORT-ND), or successor form adopted by MassHealth, in accordance with MassHealth instructions. This form serves as the detailed written order and statement of medical necessity. As a condition of payment, a copy of the completed form must be submitted to MassHealth along with the provider's claim. The completed form must be maintained in the member's record.

(2) Orthotic Services Other than Shoes. For orthotics other than shoes, shoe inserts and modifications, the detailed written order may be prepared by the provider of orthotics but must be reviewed, signed and dated by the member's prescribing provider. MassHealth medical necessity guidelines for specific orthotics require that the detailed written order be signed by specified medical professionals. The detailed written order must be maintained in the member's record. In addition to meeting the requirements in the first paragraph of 130 CMR 442.409(B), the detailed written order must include, at minimum, the following information:

(a) the member's name and address;

(b) the member's MassHealth identification number;

(c) specific identification of the prescribed item, including all options or additional features that will be separately billed;

(d) the member's diagnosis;
(e) a statement of medical necessity;
(f) the prescribing provider's address and telephone number; and
(g) the date on which the prescribing provider signed the detailed written order.

(C) Exception for Repairs of Items Purchased by MassHealth. The MassHealth agency does not require an initial order or a detailed written order for the repair of an orthotic by the provider who initially supplied the item to be repaired.

442.410: Orthotic Services Provided to Members in Facilities

(A) Nursing Facilities. MassHealth pays for the purchase and repair of orthotics provided for the personal exclusive use of a member residing in a nursing facility.

(B) Hospitals. MassHealth does not pay orthotics providers for the purchase or repair of orthotics provided to a hospitalized member, except for orthotics that are prescribed for home use after discharge. The orthotics provider must document the member's discharge plan in the member's record. Documentation must indicate that the date of discharge was the date the claim was submitted for the purchase or repair of the prescribed item.

(C) Intermediate Care Facilities for the Intellectually Disabled (ICF/IID).
(1) MassHealth pays orthotics providers for the purchase and repair of custom-fabricated orthotics provided for the personal exclusive use of a member residing in an ICF/IID only if the customization precludes the use of the item by subsequent residents in that institution.
(2) MassHealth does not pay orthotic providers for the purchase or repair of orthotics that are not custom-fabricated provided to a member residing in an ICF/IID, except for therapeutic shoes for diabetics, modifications and inserts, and associated repairs, provided for the personal exclusive use of a member residing in the ICF/IID.

(D) Date of Service for Delivery to Facilities. 130 CMR 442.424 governs the date of service to be used for claims for orthotics delivered to members in facilities.

442.411: Repairs of Orthotic Products

(A) MassHealth covers repairs subject to prior authorization under 130 CMR 442.412(F). MassHealth may cover, at its discretion, repair of an item only if the repair is less than the cost to replace the item.

(B) The provider of orthotics is liable for the quality of the workmanship and parts, and for ensuring that repaired item is in proper working condition.

(C) The provider of orthotics must exhaust all manufacturer warrantees before submitting claims for repairs to orthotics to the MassHealth agency.

442.412: Prior Authorization

The orthotics provider must obtain prior-authorization (PA) from the MassHealth agency or its designee for all orthotics or orthotic services identified as subject to PA in the MassHealth Orthotics and Prosthetics Payment and Coverage Guidelines Tool or other guidance specified by MassHealth or its designee, or as otherwise required by 130 CMR 442.000 and 130 CMR 450.303: *Prior Authorization*. Prior authorization is a determination of medical necessity only, and does not establish or waive any other prerequisites for payment, such as member eligibility or requirements to seek payment from other liable parties.

(A) Documentation of Medical Necessity.

(1) PA requests must include:

(a) a completed MassHealth Prior Authorization Request form (the MassHealth PA-1 form adopted by MassHealth or its designee);

(b) a detailed written order that meets the requirements of 130 CMR 442.409(B);

(c) for all orthotics that are identified as requiring individual consideration (IC) in the pricing regulation, 101 CMR 334.00: *Protheses, Prosthetic Devices and Orthotic Devices* and which are also identified as subject to prior authorization in *the Orthotics and Prosthetics Payment and Guidelines Tool*, Subchapter 6,or in other guidance issued by MassHealth or its designee:

1. a copy of the original invoice, if applicable, that reflects all discounts to be applied to determine the provider's adjusted acquisition cost as defined in 101 CMR 334.02: *Prostheses, Prosthetic Devices and Orthotic Devices*; or

2. if the item has not been purchased by the provider at the time of the prior authorization request, or when the item being purchased is not an item that the provider normally purchases within its scope of business, MassHealth will accept a quote from the provider's supplier. The quote must be on the supplier's letterhead or form and must be addressed to the provider; and

3. any additional assessments of the member or other necessary information requested by the MassHealth agency or its designee, in support of the request for prior authorization.

(B) 90-day Requirement for Submission of Prior Authorization Requests. The provider must submit the request for PA to MassHealth or its designee no later than 90 calendar days from the date the prescribing provider signed the detailed written order. Failure to submit the PA request within the 90-day period will result in a denial of the prior authorization request.

(C) Prior Authorization Requests for Units in Excess of the Maximum Allowable Units. MassHealth requires PA for orthotics provided to the member if the number of units requested exceeds the maximum units described in the Orthotics and Prosthetics Payment and Coverage Guidelines Tool.

(1) The provider must include documentation that supports the medical necessity of the additional units;

(2) If the PA request is authorized by MassHealth or its designee, the provider must submit a separate claim with a different date of service than the date of service for the initial maximum number of units only for the number of excess units actually provided to the member, but in no case for a number of units that exceeds the excess units for which a PA has been authorized.

(D) Prior Authorization Required before Delivery of Product. Orthotics providers must obtain prior authorization from MassHealth or its designee before delivery of a product to a MassHealth member.

(E) Prior Authorization Requests for Members Who Have Other Insurance. For members for whom MassHealth is not the primary insurer and for whom the provider is seeking payment from another insurer, the provider must make diligent efforts to first identify and obtain payment from all other liable parties, including Medicare, before seeking payment from MassHealth in accordance with 130 CMR 450.316: *Third-party Liability: Requirements*.

(F) Repairs of Orthotics. Providers must consult the Orthotics and Prosthetics Payment and Coverage Guidelines Tool, or other guidance as issued by MassHealth or its designee, to determine when PA is required for the repair of orthotics.

(1) PA is required for repairs as indicated in the Orthotics and Prosthetics Payment and Coverage Guidelines Tool, including, but not limited to, repairs exceeding $1,000:

(2) The orthotics provider must submit the following documentation with the PA request:

(a) a completed MassHealth Prior Authorization Request (the MassHealth PA-1 form, adopted by MassHealth);

(b) a detailed written order (only required if the provider requesting the repair is not the provider who initially supplied the item);

(c) an invoice or quote for the repaired or replaced item;

(d) a work order log with the estimated number of hours the repair will take;

(e) a detailed description of the circumstances that made the repair necessary; and

(f) an explanation as to why the repaired or replaced item is not covered under any warranty.

(G) Assessment. The MassHealth agency may, at its discretion, require the provider of orthotics to submit an assessment of the member's condition and the objectives of the requested service in support of a PA request. The MassHealth agency may also, at its discretion, require an evaluation by the requesting provider's ABC- or BOC-certified orthotist or pedorthist to determine whether the requested orthotic is useful to the member, given the member's physical condition and physical environment.

(H) Recordkeeping. The provider must keep the PA request on file for the period of time required by 130 CMR 450.205: *Recordkeeping and Disclosure*.

(I) Notice of Approval, Denial, or Modification of a Prior-Authorization Request.

(1) Notice of Approval. If the MassHealth agency, or its designee, approves a prior authorization request for orthotics, the MassHealth agency, or its designee will send notice of its decision to the member and the orthotics provider.

(2) Notice of Denial or Modification. If the MassHealth agency, or its designee, denies or approves with a modification, a prior authorization request for orthotics, the MassHealth agency, or its designee, will notify the member and the orthotics provider. The notice will state the reason for the denial or modification, and will inform the member of the right to appeal and of the appeal procedure in accordance with 130 CMR 610.000: *MassHealth: Fair Hearing Rules*.

(3) Right of Appeal. A member may appeal a service denial or modification by requesting a fair hearing in accordance with 130 CMR 610.000: *MassHealth: Fair Hearing Rules*.

(4) Notice of Deferral. If the MassHealth agency, or its designee defers a prior authorization request due to an incomplete submission or lack of documentation to support medical necessity, the MassHealth agency, or its designee will notify the orthotics provider of the deferral, and the reason for the deferral and provide an opportunity for the provider to submit the incomplete or missing documentation. If the provider does not submit the required information within 21 calendar days of the date of deferral, the MassHealth agency, or its designee will make a decision on the prior authorization request using all documentation and forms submitted to the MassHealth agency, and will send notice of its decision to the provider and the member in accordance with 130 CMR 442.412 (I).

442.413: Medical Necessity Criteria

(A) All orthotics covered by MassHealth must meet the medical necessity requirements set forth in 130 CMR 442.000, and 450.204: *Medical Necessity*, in the Orthotics and Prosthetics Payment and Coverage Guidelines Tool, and in any other medical necessity guidelines for specific orthotics issued by MassHealth or its designee.

(B) For items covered by MassHealth, for which there is no MassHealth item-specific medical necessity guideline and for which there is a Medicare LCD policy developed by CMS indicating Medicare coverage of the item under at least some circumstances, the provider must demonstrate medical necessity of the item consistent with the Medicare LCD. However, if the provider believes the orthotic is medically necessary even though it does not meet the criteria established by the LCD, the provider must demonstrate medical necessity under 130 CMR 450.204: *Medical Necessity*.

(C) For an item covered by MassHealth, for which there is no MassHealth item-specific medical necessity guideline and for which there is a Medicare LCD indicating that the item is not covered by Medicare, the provider must demonstrate medical necessity under 130 CMR 450.204: *Medical Necessity*.

442.414: Medicare and Other Third-party Coverage

(A) For members with Medicare and other third-party-liability coverage, see 130 CMR 450.316 through 450.318.

(B) When Medicare or another third party payer denies a claim for orthotic services, the provider is required to have a MassHealth prior authorization (PA) in place for all orthotics the MassHealth agency, or its designee identifies as subject to PA in the MassHealth *Orthotics and Prosthetics Payment and Coverage Guidelines Tool* or other guidance specified by MassHealth or its designee, or as otherwise required by 130 CMR 442.000 or 130 CMR 450.303: *Prior Authorization*.

(C) The MassHealth agency, or its designee, may request documentation of a provider's diligent efforts to collect payment from Medicare or other liable parties, including documentation of compliance with Medicare's billing and authorization requirements. If documentation requested by the MassHealth agency, or its designee is not received within the timeframe specified, or the documentation is incomplete or does not support payment by MassHealth, the associated claims will be denied. If the MassHealth agency determines that a provider did not make diligent efforts to bill other insurances and that other liable parties should have been billed, the provider will be subject to audits.

(130 CMR 442.415 Reserved)

442.416: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary orthotics or orthotic services for EPSDT-eligible members in accordance with 130 CMR 450.140: *Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Services: Introduction*, without regard to service limitations described in 130 CMR 442.000, and with prior authorization pursuant to 130 CMR 442.412.

(130 CMR 442.417 and 442.418 Reserved)

442.419: Quality Management and Program Integrity

Orthotics providers shall comply with applicable CMS and MassHealth quality standards and participate in any quality measurement program requirements established by the MassHealth agency including making any necessary data available and providing access to the provider's place of business upon request by MassHealth or its designee.

442.420: Conditions of Payment

(A) The MassHealth agency pays for orthotics in accordance with the applicable payment methodology and rate schedule established by EOHHS at 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices*.

(B) Providers of orthotics must accept MassHealth payment as payment in full for orthotics and orthotic services according to the rates established by EOHHS at 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices*.

(C) Payments are subject to the conditions, exclusions, and limitations set forth in 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*.

(D) An Initial Order is not a condition of payment. As set forth in 130 CMR 442.420(D)(1) through (5), a Detailed Written Order is a condition of payment. MassHealth pays for orthotics only if:

(1) the MassHealth agency, or its designee determines that the orthotics are medically necessary;
(2) the member meets the clinical eligibility criteria for the orthotics;
(3) the provider has obtained a detailed written order in accordance with 130 CMR 442.409;
(4) the provider has obtained prior authorization, if necessary, in accordance with the requirements set forth in 130 CMR 442.412; and
(5) the provider has diligently sought payment from all other liable parties in accordance with 130 CMR 442.405(I) and 130 CMR 450.000: *Administrative and Billing Regulations*.

442.421: Claims for Items Priced at Individual Consideration

The MassHealth agency will not accept a quote attached to a claim for orthotics that are identified in 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices;* the Orthotics and Prosthetics Payment and Guidelines Tool*;* or in other guidance issued by MassHealth, as requiring individual consideration (I.C.). For items designated as I.C., the provider must:

(A) attach the actual manufacturer's invoice dated within six months of the prior authorization request to the claim submission;

(B) not accept a printed invoice or order from a manufacturer's web site; and

(C) keep a copy of the quote and the invoice on file.

(130 CMR 442.422 Reserved)

442.423: Recordkeeping Requirements

The orthotics provider must keep a record at the service facility for each member for all orthotics and orthotic services provided to a member. The record must include documentation of all purchases and repairs of all orthotics provided for each member in accordance with the recordkeeping requirements set forth in 130 CMR 450.205: *Recordkeeping and Disclosure*. The orthotics provider must make all records retained in accordance with 130 CMR 450.205: and 130 CMR 442.000 available to the MassHealth agency or its designee upon request. Payment for services is conditioned upon the complete documentation in the member's record. In addition to fulfilling the requirements of 130 CMR 450.205, the provider must ensure that each member's record includes the following:

(A) a copy of the initial order if applicable (or written documentation of a verbal initial order) that meets the requirements set forth in 130 CMR 442. 409(A) and a completed, signed, and dated detailed written order that meets the requirements set forth in 130 CMR 442.409(B) and any other applicable state or federal law or regulation;

(B) a copy of each prior authorization request submitted to the MassHealth agency or its designee on behalf of the member, including all related documentation submitted with the request, and all correspondence with the MassHealth agency or its designee and the MassHealth agency decision related to each such request;

(C) if the member has third-party liability, the provider must also maintain a copy of all documentation of their efforts to diligently seek prior authorization and payment from other liable parties.

(D) the actual invoice showing the cost to the provider of the orthotic (if the provider is not the manufacturer of the orthotic); and

(E) an acknowledgement of receipt, signed by the member or the member's representative, of the prescribed orthotics or orthotic service, including:

(1) the date of receipt of the item(s) and location of delivery;

(2) a sufficiently detailed description to identify the item(s) being delivered (such as, brand name, HCPCS code, and narrative description).

(3) for repair services, a complete description of the service, including the manufacturer, and if applicable, brand name, model number, and serial number of the repaired item; and

(4) if the member's representative signs, next to the signature, an explanation of the representative's relationship to the member by the individual acknowledging receipt. This individual cannot be associated with the provider.

(a) a signature stamp and/or member's mark may be used by a MassHealth member whose disability inhibits the member's ability to write.

(b) a signature stamp may only be used by a member or the member's representative, provided that the stamp is used by the member in his or her normal course of conducting business. A signature stamp cannot be used by anyone associated with the provider.

(F) documentation demonstrating the cost of manufacturing the orthotic provided, including all raw materials, (if the provider is the manufacturer);

(G) for repair services, a complete description of all repair services, including the manufacturer, brand name, and model number of the repaired item;

(H) documentation of a member's other insurance and any documentation submitted to and received from other insurers;

(I) documentation of any oral or written complaints received from the member or submitted on behalf of the member in accordance with 130 CMR 442.405(Q). The documentation must include, at a minimum:

(1) the name, address, and telephone number of the member;
(2) the name, address, and telephone number of the person filing the complaint (if not the member);
(3) a summary of the complaint;
(4) the date the complaint was received by the provider;
(5) the name of the person receiving the complaint; and
(6) a summary of any investigation or actions taken by the provider of orthotics to resolve the complaint.

442.424: Delivery of Orthotics

(A) Proof of Delivery. Orthotics providers must maintain proof of delivery (POD) in the member's medical record. POD documentation must be made available to the MassHealth agency upon request. Orthotic providers may use one of three methods to deliver orthotics to the member: direct delivery; delivery *via* shipping; or delivery in anticipation of hospital discharge. The orthotics provider, in conjunction with the member or their designee, will determine the method of delivery.

(B) Timelines of Delivery. The orthotics provider must ensure that orthotics are delivered within a reasonable time after receipt of the detailed written order and any required documentation or approval for the item. This includes referring the member to another orthotics provider, when timely delivery cannot be made by the current orthotics provider. The MassHealth agency, or its designee, reserves the right to issue additional subregulatory guidance on reasonableness of delivery times for customized orthotics and specific orthotic items.

(C) Direct Delivery. The orthotics provider may deliver the orthotic product directly to the member or dispense the product to the member at the provider's service location. In this case the POD must be a signed and dated delivery slip. The POD documentation must include:

(1) member's name;
(2) sufficiently detailed description to identify the item(s) being delivered (such as, brand name, HCPCS code, narrative description);
(3) quantity delivered;
(4) date delivered; and
(5) member (or member's designee) signature and date of signature. The date of signature on the delivery slip must be the date that the orthotic product was received by the member or member's designee.
(6) In instances of direct delivery, for purposes of filing a claim for payment, the date of service on the claim must be the date the member received the orthotics, as evidenced by the date of the member's (or member's designee) signature on the delivery slip.

(D) Delivery *via* Shipping Service.

(1) Providers of orthotics may use a shipping service to deliver orthotic products.

(2) If the provider of orthotics utilizes a shipping service, the POD documentation must include a complete tracking record. An example of acceptable POD would include both the provider's own detailed shipping invoice and the shipping service's tracking information. Providers may also utilize a return postage-paid signed shipping invoice from the member or the member's designee as evidence of POD. The POD record must include:

(a) member's name;

(b) delivery address;

(c) shipping service's package identification number, orthotics providers' invoice number or alternative method that links the provider of orthotics' delivery documents with the shipping service's records;

(d) sufficiently detailed description to identify the item(s) being delivered (*e.g.*, brand name, serial number, narrative description);

(e) quantity delivered;

(f) date delivered; and

(g) evidence of delivery;

(3) If a provider of orthotics utilizes a shipping service, for purposes of filing a claim for payment, the date of service is the date the orthotics was shipped to the member.

(E) Delivery to Members in a Facility. Delivery to members in facilities and to members being discharged from facilities to a community dwelling;

(1) Delivery of orthotics products to a nursing facility or ICF/IID on behalf of a member:

(a) Providers of orthotics may deliver orthotics for a member directly to a nursing facility or ICF/IID. When the provider of orthotics delivers items directly to a nursing facility or ICF/IID, the documentation described in 130 CMR 442.424(C) is required. When a shipping service is used to deliver the item to a nursing facility or ICF/IID, the documentation described in 130 CMR 442.424(D) is required.

(b) The date of service on the claim must be the date as specified in 130 CMR 442.424(C)(2) or 130 CMR 442.424(D)(2), as applicable.

(2) Delivery in anticipation of discharge from a hospital:

(a) A provider of orthotics may deliver an orthotic product to a patient in a hospital for the purpose of fitting or training the patient in the proper use of the item. This may be done up to two days prior to the patient's anticipated discharge.

(b) The date of service for purposes of filing a claim for payment is the date of discharge with the member's home as the place of service (POS).

(c) The provider of orthotics may not bill MassHealth for days prior to discharge, such as days the patient was receiving training or fitting in the hospital.

442.425: Prohibited Marketing Activities

An orthotic provider shall not:

(A) with the knowledge that a member is enrolled in a MassHealth capitated program, engage in any practice that would reasonably be expected to have the effect of steering or encouraging the member to disenroll from the MassHealth capitated program in order to retain the provider to provide services on a fee-for-service basis; or

(B) offer to a member, or his or her family or caregivers, in-person or through marketing any inducement to retain the provider to provide orthotic services, such as a financial incentive, reward, gift, meal, discount, rebate, giveaway, or special opportunity;

(C) pay a "finder's fee" to any third-party in exchange for referring a member to the orthotic provider; or

(D) engage in any unfair or deceptive acts or practices in connection with any marketing.

REGULATORY AUTHORITY

130 CMR 442.000: M.G.L. c. 118E, §§ 7 and 12

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